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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,052	06/29/2001	Frank J. Bunick	MCP-281	9476

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,052

Applicant(s)

BUNICK ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of.
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.
37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's petition for extension of time, request for continued examination, amendment, and response, all received on 17 November 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-25 under 35 U.S.C. 103(a) as being unpatentable over Mehta in view of Lee is withdrawn.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lee and Friend *et al.* (U.S. Patent No. 6,139,865)

Lee teaches a chewable pharmaceutical dosage form comprising of a core containing an active ingredient, and an outer layer (See Figure 2). The dosage form demonstrates improved organoleptic properties when chewed, such as taste (See Column 1, Lines 47-52). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See Column 2, Lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form (See Column 2, Lines 59-61). The outer layer may take a variety of forms, including hard candy (See Column 2, Lines 34-42). Acetaminophen is listed as a possible active ingredient in core (See Column 2, Lines 9-18). In

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addition, Lee contains what the examiner will interpret as an enabling disclosure of a dosage form with a unitary core (See Figure 2; and MPEP § 2125).

The Friend *et al.* patent teaches taste-masked microcapsule compositions for the administration of a drug (See Abstract). Drugs to be used in the disclosed compositions include acetaminophen and ibuprofen (See Column 4, Lines 28-37). The compositions may be incorporated into a variety of dosage forms, including chewable tablets, in amounts ranging from 10% to 95% by weight of the dosage form (See Column 4, Lines 55-65; and Column 9, Line 56 to Column 10, Line 25). It is preferred that the microcapsules range in size from approximately 30 microns to 800 microns (See Column 8, Line 30-36).

It would be obvious to one of ordinary skill in the art to combine the teachings of Lee and Friend *et al.* into the objects of the instant application. Both the Lee and Friend *et al.* patents deal with the administrations of drugs in pharmaceutical compositions with improved organoleptic properties. Therefore, one of ordinary skill would be motivated to incorporate the composition disclosed in Friend *et al.* into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug. As Friend *et al.* states that the disclosed compositions may be incorporated into chewable tablets, it is the position of the examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success.

Claim limitations drawn to features such as hardness of the soft core and the weight ratio of active agent particles to the outer shell are not considered by the examiner to be critical features. It is unclear how such features contribute to the improved organoleptic properties of

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the instantly claimed dosage form. The examiner shifts the burden onto the applicant to demonstrate how these features are critical and would not have been obvious to one of ordinary skill in the art.

Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive.

It is the position of the examiner that the applicant's arguments are based upon a narrow interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123. In the view of the examiner, such an interpretation is proper and is not, as the applicant alleges, mere speculation. The prior art therefore reads on the claims, and the claimed invention, as a whole, is *prima facie* obvious.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sj0


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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